K133296

FEB 14 2014

510(k) Summary
807.92(c)

SPONSOR **807.92(a)(1)**

Company Name:	ALSEAL
Company Address	2 rue Paul Milleret 25000 Besançon France
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Contact Person:	Jean-François DELFORGE

Summary Preparation Date: September 29, 2013

DEVICE NAME **807.92(a)(2)**

Trade Name:	XCath (Model 2064-XC)
Common/Usual Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
Regulation Number:	870.1340
Product Code:	DYB
Device Class:	Class II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

K Number	Product Name	Manufacturer
K113849	HQS Introducer	ALSEAL
K121185	Edwards Percutaneous Sheath Introducer	Edwards Life Sciences, LLC

DEVICE DESCRIPTION **807.92(a)(4)**

The XCath (model 2064-XC) consists of a multiple ways access (2, 3 or 4 ways) adapted to the HQS Introducer (K113849) to optimize the sealing when several vascular tools up to 9,3F need to be introduced through the same vascular access.

The device features include (1) a flexible multilumen body, with 2, 3 or 4 channels compatible with the open valve of HQS Introducer; (2) a base with 2, 3 or 4 valves, (3) Extension line for each valve with stopcock and Luer Lock connection.

Once the XCath is connected to the body of the HQS Introducer, the device can accommodate vascular tools up to 9,3 French (3,1mm). The XCath (accessory) is fixed in proximal position of the HQS introducer body and allows the simultaneous insertion of several vascular tools.

DEVICE INDICATIONS FOR USE **807.92(a)(5)**

XCath (model 2064-XC) is intended to be inserted into the HQS Introducer (model 2064-HQS) to establish multiple and simultaneous conduits through the same vascular access (previously established by the HQS introducer).

The whole XCath / HQS allows insertion of several endovascular devices at the same time while minimizing blood loss associated with such insertions.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

	Subject Device	Predicate Device	Predicate Device
Manufacturer	ALSEAL	ALSEAL	Edwards Life Sciences, LLC
Trade Name	XCath (model 2064-XC)	HQS Introducer	Edwards Percutaneous Sheath Introducer AVA 3Xi and AVA High Flow
K number		K113849	K 121185
Product Code	DYB	DYB	DYB
Regulation No.	870.1340	870.1340	870.1340
Indications for Use	XCath (model 2064-XC) is intended to be inserted into the HQS Introducer (model 2064-HQS) to establish multiple and simultaneous conduits through the same vascular access (previously established by the HQS introducer). The whole XCath / HQS allows insertion of several endovascular devices at the same time while minimizing blood loss associated with such insertions.	The HQS Introducer (Model 2064-HQS) is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions	The Edwards Percutaneous Sheath Introducer is indicated for use in patients requiring access of the venous system and to facilitate catheter insertion (e.g. pulmonary artery or infusion catheter).
Principle of Operation	Transitions the HQS with a single insertion into a multi lumen device based on the number of access conduits required by the use of multiple silicone valves.	The tools are introduced in the vasculature by placing a guide through the device and going through a silicone valve minimizing blood loss	Transitions from an introducer to a triple lumen device with a fixed or detachable introducer valve as treatment changes accomplished through single percutaneous introducer
Device Design	Each channel of XCath accessory has an approaching design of HQS introducer (sheath equipped with a silicone valve and a lateral	Sheath equipped with a silicone valve and a lateral extension line with Luer Lock connectors / 3 way stopcock.	Introducers are composed of valve housing to which a sheath is attached distally and three side arm/extension tubes are connected proximally.

	extension line with Luer Lock connectors / 3 way stopcock).	Furnished with a dilator for facilitating the introduction into vasculature.	The valves located in the housing body provide a seal around a catheter when inserted through the introducer and prevent backflow when no catheter is present
Number of channels for vasculature access	As an accessory to the HQS Introducer: 2 way 3 way 4 way	1 channel Introducer	Triple lumen with 4th access via the fixed or detachable introducer valve
Valve comparison	Silicone valve ensures sealing while empty or accessed with guide / max dilator.	Silicone valve ensures sealing while empty or accessed with guide / max dilator	Valve ensures sealing while empty or insertion eased with provided dilator
Biocompatibility Testing	ISO 10993-1 for External communicating device, direct circulating blood path, duration ≥ 24 hours	ISO 10993-1 for External communicating device, direct circulating blood path, duration ≥ 24 hours	ISO 10993-1 for External communicating device, direct circulating blood path, duration ≥ 24 hours
Sterilization	Provide sterile; Single use.	Provide sterile; Single use.	Provide sterile; Single use.

NON-CLINICAL PERFORMANCE DATA **807.92(b)(1)**

SAFETY BENCH TESTING

In accordance with ISO 10993-1, XCath (Model 2064-XCath) is categorized as externally communicating devices in contact with circulating blood for less than 24 hours. The following tests are recommended by ISO 10993-1.

PERFORMANCE TESTING

The following in vitro testing was performed on the XCath (Model 2064-XCath) in accordance with ISO standards and/or internal procedures to assure reliable design and performance. In vitro design verification testing data demonstrates that the device is in compliance with ISO 11070: 1999 Sterile, single use intravascular catheters introducers and product labeling.

1. Tensile strength
2. Overpressure resistance
3. Dimensions and aspect
4. Sealing resistance
5. Air leak (vacuum) test
6. Compatible with HQS introducer
7. Sealing of the valve
8. Free passage a guide and 9F vascular tool
9. Validation of luer and extension lines
10. Ease of assembly
11. Traction resistance
12. Packaging resistance

13. Sterilization tests
14. Aging tests

CONCLUSION **807.92(b)(3)**

XCath (model 2064-XC) is substantially equivalent to the predicate device in Indications for Use, Materials and design. Safety and performance testing to ISO 11070 and Biocompatibility testing has concluded that the device does not introduce significant questions of safety and efficacy and is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -
WO66-G609
Silver Spring, MD 20993-0002

February 14, 2014

Alseal
C/O Yolanda Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114 US

Re: K133296
Trade/Device Name: XCath Model 2064-XC
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer Accessory
Regulatory Class: Class II
Product Code: DYB
Dated: January 8, 2014
Received: January 10, 2014

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801) please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133296

Device Name
XCath (Model 2064-XC)

Indications for Use *(Describe)*

XCath (model 2064-XC) is intended to be inserted into the HQS Introducer (model 2064-HQS) to establish multiple and simultaneous conduits through the same vascular access (previously established by the HQS introducer).

The whole XCath / HQS allows insertion of several endovascular devices at the same time while minimizing blood loss associated with such insertions.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*